UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,648	02/12/2007	Masaru Tanaka	4252-0119PUS1	5783

2292 7590 07/07/2010

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
IWAMAYE, ANDREW MICHAEL	
ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
07/07/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,648	TANAKA ET AL.	
	Examiner	Art Unit	
	ANDREW IWAMAYE	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,15,20-23 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,14,15,20-23 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to **claims 11, 14-15, 20-23**, and **26** have been considered but are moot in view of the new ground(s) of rejection.

The newly amended claims have been rejected mainly over the teachings of Makoto, Nishikawa, and Masaru. Makoto clearly teaches a porous film having a non-biodegradable resin. In the rejections that follow, the non-biodegradable resin of Makoto is used in the honeycomb-film-production-methods taught by Nishikawa and Masaru.

Examiner realizes that Nishikawa teaches a biodegradable resin to be used in the production method. However, Masaru clearly teaches that the same production method can employ either degradable or non-degradable resins to successfully form honeycomb structures (see [0009]). As such, the use of the non-biodegradable resin of Makoto to form a honeycomb structure would have been well within the technical grasp of one having ordinary skill in the art.

Claim Objections

2. **Claims 11, 14-15, 20-23,** and **26** are objected to because of the following informalities:

In **claim 11:**

- Line 4, as presently worded, is confusing. It is unclear if the recitation of "its" is referring to the medical instrument substrate or if it is referring to the film.

In **claim 15:**

- Line 2, as presently worded, is confusing. It is unclear if the recitations of "a resin" and “a substrate” are referring to the resin and substrate in claim 11.
- In line 3, there is lack of antecedent basis for the recitation of "the cast solution".

In **claim 23:**

- Lines 2-3, as presently worded, are confusing. It is unclear if the recited film, resin, and porous structure are referring to the film, resin, and porous structure in claim 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. **Claims 11, 14-15,** and **20-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Makoto et al (JP 2001-327609) in view of Nishikawa et al ("Fabrication of Honeycomb Film of an Amphiphilic Copolymer at the Air-Water Interface"), and further in view of Masaru et al (JP 2003-149096).

Regarding **claims 11** and **20-22**, Makoto et al (Makoto) teaches a biliary ([0001]) **stent** 2 (i.e. **a medical instrument**) **comprising** a stent surface (i.e. **a medical instrument substrate**), **and a film** 14/15 **including a non-biodegradable** polyolefin **resin and having a porous structure formed at least on its surface** ([0022]-[0023]), **the surface of the medical instrument being entirely or partially covered with the film** (see Figures), **pores of the porous structure of the film have an average pore size of** 0.1-10μm (i.e. within the range of **0.1 to 20μm**) (see [0023]) **and the thickness of the film is** 10-200μm (i.e. within the range of **0.5 to 20μm**) (see [0022]). Makoto further teaches the pores of the film to be designed to prevent invasion of tissue into the film and stent ([0002] and [0023]). Thus the film of the Makoto is cell-growth-inhibiting film.

Makoto fails to explicitly teach a **honeycomb structure** and **an amphiphilic substance**.

However, Nishikawa et al (Nishikawa) teaches a unique to process of making a porous film. The film that is produced includes a resin, **an amphiphilic substance,** and a **honeycomb** porous structure formed at least on the surface (see whole document).

Nishikawa further cites a prior publication ("Mesoscopic patterning of cell adhesive substrates as novel biofunctional interfaces" by Nishikawa et al, which is already art of record), of which discloses that the honey-comb films can be tailored to inhibit cellular adhesion/proliferation by adjusting the diameters of the honeycomb pores (see pp 145, first paragraph of right column and "Conclusions" section of the cited publication).

Makoto and Nishikawa are concerned with the same field of endeavor, namely films that prevent/inhibit cellular growth.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the film of Makoto by making it from the process taught by Nishikawa (and thereby employ an amphiphilic substance with the resin to obtain a honeycomb porous structure) in order to provide an alternative, commonly known anti-cell-proliferation film. One would be further motivated to employ the production method of Nishikawa since it is more cost-saving and technologically simpler than other production techniques ("Introduction" section of Nishikawa).

Makoto and Nishikawa combination fail to teach the claimed **weight ratio**.

However, Masaru et al (Masaru) teaches honeycomb films made by the process taught by Nishikawa. The films are taught to be made from non-biodegradable resins ([0009]), such as polysulfone, and an amphiphilic substance ([0010]), wherein the **weight ratio of the amount of the non-biodegradable resin to the amount of the amphiphilic substance is** 0:1 to 1:0 (i.e. within the range of **99:1 to 50:50**) ([0011]).

Makoto and Nishikawa combination and Masaru are concerned with the same field of endeavor, namely honeycomb porous films.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the film of Makoto and Nishikawa combination by incorporating the claimed weight ratio between the non-biodegradable resin and the amphiphilic substance, as taught by Masaru, since such weight ratios are known to successfully produce honeycomb porous structures.

Regarding **claim 14**, the process of forming honeycomb porous structures taught by each of Nishikawa and Masaru results in a coefficient of variation in pores of 20% or less (see claim 1 of Masaru).

Regarding **claim 15,** the Examiner recognizes claim 15 as a "product-by-process" claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process *(In re Thorpe,* 777 F.2d 695, 698,227 USPQ 964,966).

Since Makoto, Nishikawa, and Masaru combination teach all of the structural limitations, the combination meets the claim.

Nevertheless, the film production process taught by Makoto, Nishikawa, and Masaru combination is identical to that claimed (see whole documents of Nishikawa and Masaru).

Regarding **claim 23**, Makoto, Nishikawa, and Masaru combination teach each of the claimed limitations. Refer to rejections as applied supra.

6. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Makoto et al in view of Nishikawa et al and Masaru et al, as applied above, and further in view of Lawin et al (US 2004/0111144 A1).

Regarding **claim 26**, as explained supra, Makoto, Nishikawa, and Masaru combination broadly teach the non-biodegradable resin to be a polyolefin polymer.

Makoto, Nishikawa, and Masaru combination fail to explicitly teach the polyolefin polymer to specifically be 1,2-polybutadiene.

However, Lawin et al (Lawin) teaches a stent comprising a polyolefin film, specifically 1,2-polybutadiene ([0019]).

Makoto, Nishikawa, and Masaru combination and Lawin are concerned with the same field of endeavor, namely polyolefin films for stents.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the non-biodegradable resin of Makoto, Nishikawa, and Masaru combination by employing 1,2-polybutadiene, as taught by Lawin, since this specific polyolefin was commonly known in the art to be used to form stent films.

.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW IWAMAYE whose telephone number is (571)270-7036. The examiner can normally be reached on Monday-Friday 7:30AM-5:00PM, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. I./
Examiner, Art Unit 3774
6/29/2010

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738